REMARKS

Status of the Claims

By virtue of the Listing of Claims presented herein, claims 61-67 and 69-107 are pending.

Claims 1-60 and 68 remain canceled.

Claims 69-74, 93, and 94 have been amended to depend from new claims 103, 104, 105, 106, and 107.

Claims 103, 104, 105, 106, and 107 been added and are drawn to genuses of nucleic acid molecules that: have 83 percent or greater amino acid identity to an OB polypeptide amino acid sequences set out in SEQ ID NO: ID NO:2, 4, 5, and 6; have 83 percent or greater amino acid identity to an OB polypeptide amino acid sequences set out in SEQ ID NO: ID NO:2; have 83 percent or greater amino acid identity to an OB polypeptide amino acid sequences set out in SEQ ID NO: ID NO:4; have 83 percent or greater amino acid identity to an OB polypeptide amino acid sequences set out in SEQ ID NO: ID NO:4; have 83 percent or greater amino acid identity to an OB polypeptide amino acid sequences set out in SEQ ID NO: ID NO:5; and have 83 percent or greater amino acid identity to an OB polypeptide amino acid sequences set out in SEQ ID NO: ID NO:6; respectively. The amended and new claims find basis throughout the specification as originally filed, including the claims as originally filed, and for example, at: Figure 4; page 5, lines 12 through 26; page 7, lines 5-19; page 10, lines 4 though 12; page 11, line 12 through page 12, line 24; page 27, line 18, through page 28; line 10; page 35, line 20, through page 36, line 25; page 42, lines 3-10; at page 43, lines 7-27; and at page 47, lines 12-19. Basis for new claims 89-102 may be found, for example, at page 26, lines 15-25, and at page 43, lines 7-18.

No new matter has been introduced by the amendments to the claims.

Claim Rejections

All arguments in all previous responses of record in the instant case, whether expressly indicated as such below or not, are hereby incorporated by reference and reapplied to the rejections set forth in the instant Office Action. Also, all of the Examiner's arguments/comments presented in the outstanding Office Action that are repetitions of arguments/comments presented in previous Actions are responded to, at least, by Applicants response(s) to such

arguments/comments provided in Applicants previous response(s), by way of their incorporation by reference, in addition to Applicant's comments below. The Examiner's comments/arguments that are first presented in the outstanding Office Action are expressly discussed by Applicant below.

Rejection under 35 U.S.C. § 112, first paragraph: written description

Claim 63

Claim 63 (and dependent claims 69-88) is again rejected under 35 U.S.C. §112, first paragraph, as allegedly containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The Examiner's arguments are largely identical to that offered in the previous Action; those portions are traversed for the reasons provided in previous response(s).

With respect to the Examiner's assertion that because "page 5 of the specification it is stated that 'ob polypeptides from various species **may** be homologous' (emphasis added)," "the specification fails to state that interspecies OB polypeptides are as much as greater than 80% homologous, as asserted by Applicant" in Applicant's previous response, despite the fact that, as the Examiner acknowledges, the specification discloses also the "'murine and human ob polypeptides are greater than 80% homologous.' Further, in this regard, the Examiner has failed to provide a well-reasoned and well-evidenced basis to doubt or refute the veracity of statements in Applicant's disclosure. Absent the provision of such objective evidence available in the art in the art, the Examiner's comments, are improper and do not support the rejection. Even assuming that the Examiner is correct, the issue is moot insofar as, at least, Figure 4 and other aspects of the instant disclosure provide adequate support for the claimed genus of molecules, as discussed below, and as previously presented in previous response(s). Accordingly, the rejection is traversed.

The Examiner next asserts that the claims are directed to "hypothetical proteins which differ from one another by as much as 34% between molecules," and that "the single disclosure

of 83% is not a basis for the broad claim of the range of 83% or greater amino acid sequence identity in the instant specification as filed." As stated in Applicant's previous response:

Relevant Law

The purpose behind the written description requirement is to ensure that the patent applicant had possession of the claimed subject mater at the time of filing of the application. *In re Wertheim*, 541 F.2d 257, 262, 191 USPQ 90, 96 (CCPA 1976). Further, a specification must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention, *i.e.*, whatever is now claimed. *Vas-Cath, Inc. v. Mahurkar*, 935 F.2d 1555, 1563-64, 19 USPQ.2d 1111, 1117 (Fed. Cir. 1991).

Further, by disclosing in a patent application a device that inherently performs a function or has a property, operates according to a theory or has an advantage, a patent application necessarily discloses that function, theory or advantage, even though it says nothing explicit concerning it. The application may later be amended to recite the function, theory or advantage without introducing prohibited new matter. *In re Reynolds*, 443 F.2d 384, 170 USPQ 94 (CCPA 1971); and *In re Smythe*, 480 F. 2d 1376, 178 USPQ 279 (CCPA 1973). Thus, the manner in which the specification meets the requirement is not material; it may be met by either an express or an implicit disclosure.

Analysis

An objective standard for determining compliance with the written description requirement is, "does the description clearly allow persons of skill in the art to recognize that he or she invented what is claimed." *In re Gosteli*, 872 F.2d 1008, 1012, 10 USPQ.2d 1614, 1618 (Fed. Cir.1989). The Examiner has the initial burden of presenting evidence or reasons why persons skilled in the art would not recognize in an applicant's disclosure a description of the invention defined by the claims. *In re Wertheim*, 541 F.2d 257, 265, 191 USPQ 90, 98 (CCPA 1976); *See also*, *Ex parte Sorenson*, 3 USPQ.2d 1462, 1463 (Bd. Pat.App. & Inter. 1987).

As the Examiner acknowledges by referring to the Revised Interim Guidelines for Examination of Patent Applications Under 35 U.S.C. § 112 paragraph 1, "Written Description"

Requirement (Docket No. 991027288-0264-02; OG date January 30, 2001), the inquiry for compliance with the written description requirement where claims are directed to a genus is performed by: 1) assessing the degree of variation among species within the genus, and 2) making a determination as to whether a representative number of examples are either explicitly or implicitly described in the application, as determined by assessing whether the skilled artisan would recognize that applicant was in possession of the necessary common attributes or features of the elements possessed by the members of the genus in view of the disclosed species.

To this end, as outlined in the Guidelines:

> the written description requirement for a claimed genus may be satisfied through sufficient description of a representative number of species by actual reduction to practice, reduction to drawings or by disclosure of relevant, identifying characteristics, i.e., structure or other physical and/or chemical properties, by functional characteristics coupled with a known or disclosed correlation between structure an function and structure, or by a combination of such identifying characteristics, sufficient to show the applicant was in possession of the claimed genus.

Further,

> a satisfactory 'representative number' depends on whether one of skill in the art would recognize that the applicant was in possession of the necessary common attributes or features of the elements possessed by the members of the genus in view of the species disclosed.

Rejected Claim 63 (and dependent claims 69-88), reads on, in part, a polynucleotide sequence encoding an OB polypeptide capable of modulating body weight, wherein the encoded OB polypeptide has 83 percent or greater amino acid identity to the OB polypeptide amino acid sequence set out in SEQ ID NO:2, 4, 5, or 6. The Examiner's rejection is directed to the recited structural feature – 83 percent or greater identity to SEQ ID NO: 2, 4, 5, or 6 of the OB polypeptides which constitute a portion of the fusion proteins encoded by the claimed genus of nucleic acid molecules, and the recited capability of modulating body weight of such OB polypeptides. Accordingly, Applicant's comments responsive to the rejection are directed to the OB polypeptide moieties that are encoded by the nucleic acids encompassed by the claimed genus.

The instant specification, for discloses, for example, that: (1) interspecies OB

polypeptides homology is high, and as much as greater than 80% homologous (see, e.g., page 5, lines 24-26); (2) the primary sequences of mouse and human OB polypeptides identified in vivo and disclosed in full by Applicant (SEQ ID NOS: 2 and 4 respectively) share 83% amino acid sequence homology (notwithstanding an inadvertent typographical error in which "83%" was typed as "84%" as explained in Applicant's response to a previous Office Action; also see e.g., Figure 4 and page 12, lines 6-14); (3) both mouse and human OB polypeptides (SEQ ID NOS: 2 and 4, respectively) are capable of modulating body weight when administered to ob/ob mice and wild-type mice (e.g., page 5, lines 10-11 and in the Examples, throughout); (4) OB-encoding polynucleotides of essentially the same size as the disclosed mouse OB polynucleotide sequence were isolated and identified based on high homology to an entire exon (SEQ ID NO:7) of the mouse OB-encoding sequence (see, e.g. Figure 16 and page 93, lines 21-28); (5) mouse and human OB polypeptide polymorphic forms exist in vivo, characterized by deletion of glutamine at position 49 (see, e.g., Figures 5 and 6, page 12, lines 15-24, and SEQ ID NOS: 5 and 6); and (6) each identified mouse and human polypeptide demonstrated to be cleaved to remove an N-terminal 21-amino acid signal sequence (see, e.g. page 12 and Figures 3, 4, 5 and 6), assays for weight-modulatory and food intake inhibition activity of OB polypeptides, and exemplary results obtained therefrom (see, e.g., pages 112-116, and Figures 28A-28D). Therefore, Applicant has described multiple OB polypeptides possessing weight modulatory capability a common functional feature, and possessing from zero (0) percent to 17% amino acid sequence variability, respectively (i.e., possess 100% and as little as 83% amino acid sequence homology relative to one another) as a common structural feature, as well as weight modulatory capability as a common functional feature.

Accordingly, the inquiry with respect to item 1) above reveals that there is little substantial degree of variation between species within the claimed genus: OB polypeptides capable of modulating body weight, which possess 83 percent amino acid sequence identity to mouse or human OB polypeptide sequences (SEQ ID NOS:2, 4, 5, or 6).

Thus, contrary to the Examiner's assertion that "what is being claimed is a genus of molecules which were never described in the instant application," (outstanding Office Action, page 4, lines 11-12) the small degree of variation within the claimed genus, is fully exemplified

and described in the instant application as filed.

The assessment with respect to item 2) of the inquiry similarly reveals that the instant application describes a representative number of examples, either explicitly or implicitly, such that the skilled artisan would recognize that Applicant was in possession of the necessary common attributes or features of the elements possessed by the members of the genus in view of the disclosed species. In this regard, and as explained in previous responses as well in the analysis above, the instant application provides an amino acid sequence alignment of mouse and human OB polypeptides, and indicates 28 positions at which differences between the sequences are observed, which translates to 83% sequence identity between the two sequences (see, e.g. Figure 4). Figure 4 thus implicitly and inherently demonstrates, as the skilled artisan would recognize, OB polypeptides that differ from either the mouse or human sequence depicted in Figure 4 by one, two, three, four, five, six, seven, eight, nine, 10, 11, 12, 13, 14, 15, 16, 17, 18, 19, 20, 21, 22, 23, 24, 25, 26, 27, or 28 amino acids, corresponding to OB polypeptide sequences possessing 99.4%, 98.8%, 98.2%, 97.6%, 97.0%, 96.4%, 95.8%, 95.2%, 94.6%, 94.0%, 93.4%, 92.8%, 92.2%, 91.6%, 91.0%, 90.4%, 89.8%, 89.2%, 88.6%, 88.0%, 87.4%, 86.8%, 86.2%, 85.6%, 85.0%, 84.4%, 83.8%, or 83.0%, respectively. A simple calculation to determine the amount of OB polypeptides possessing from one to 28 amino acids which differ from either the mouse or the human sequence of Figure 4 reveals that 28^{20} OB polypeptides possessing at least 83% identity are implicitly described by virtue of the disclosure of Figure 4.

In the outstanding Action, the Examiner does not rebut the inherent disclosure demonstrated by Applicant. The inherent disclosure provides ample and representative species that are encompassed by the claimed genus of molecules. Furthermore, these species are not merely "hypothetical" as the Examiner characterizes them, insofar as they are adequately described in terms of structural, functional, and chemical and physical attributes such that a person of skill in the art, equipped with Applicant's disclosure in conjunction with knowledge and technical capabilities in the art at the time of filing, would recognize that Applicant was in possession of the claimed invention at the time of the effective filing date. Therefore, the Examiner's rejection is again traversed

The Examiner's assertion that Applicant's did not "have possession of the nucleic acid

molecules encoding that were identified by hybridization to the G27 probe" and that because the "claims do not require the G27 probe, Applicant is "arguing limitation not present in the claims." The Examiner continues, asserting that "Applicant has not equated nucleic acid hybridization with encoding a protein of a particular function. Furthermore, a method of isolating a molecule is not a written description of the molecule." Applicant's traverse for the reasons provided in previous response(s), as well as those provided below, at least.

Contrary to the Examiner's assertions, the Applicant's comments do not constitute a "arguing a limitation that is not present in the instant claims." Applicant's comments merely direct the Examiner's attention to certain species that are encompassed by the claimed genus and the demonstration as to how and where they were disclosed in the instant specification. In this regard, the Examiner is reminded that "How the specification meets the requirements of section 112 is not material." *In re Herschler*, 591 F.2d 693 (CCPA, 1979). Thus, it is incorrect and improper for the Examiner to construe the manner in which Applicant has described certain species encompassed by the claimed genus, and Applicant's comments with respect thereto, as an attempt to "argue limitation not in the claims". Furthermore, that a "particular function" is associated with these molecules is readily appreciated by the skilled artisan insofar as, at least, these isolated nucleic acid molecules were isolated under conditions that the skilled artisan would recognize demonstrates their identity as ob polypeptides; as such, as the skilled artisan would understand based on the disclosed and demonstrated weight modulatory function of ob polypeptides, that the isolated nucleic acid molecules encode polypeptides possessing weight – modulatory function. Thus, considered with the totality of Applicant's entire disclosure, the instant specification conveys with reasonable clarity to those skilled in the art that, as of the filing date, Applicant was in possession of these weight modulatory isolated nucleic acid molecules.

Furthermore, the Examiner is reminded that the results obtained with the G27 probe are not the sole basis upon which evaluation of Applicant's disclosure with respect to satisfactory written description of the claimed genus of molecules rests, and are to be considered in conjunction with all aspects of Applicant's disclosure. In this regard, and as articulated above as well as in Applicant's previous response, the disclosure of the instant Applicant taken in totality provides ample explicit and inherent disclosure of a large number of representative ob

polypeptide proteins that are encompassed by the claimed genus such (~28^{20}) such that the instant specification conveys with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. Thus, even assuming *arguendo* that the Examiner's assertions are correct with respect to those particular species identified by hybridization to the G27 probe, the claimed genus of molecules nonetheless still enjoys sufficient written description support. Thus, the Examiner's comments are unavailing and do not support the rejection.

Accordingly, the rejection is in error and should be withdrawn.

Claims 61-62

Claims 61-62 are rejected under 35 U.S.C. § 112, first paragraph, as allegedly failing to comply with the written description requirement. Specifically, the Examiner asserts that the phrase, "wherein said OB polypeptide comprises an amino acid sequence set out in" allegedly "encompasses any and all sequences which could be made from the reference of SEQ ID NO:2, 4, 5, or 6 – this includes fragments and non-contiguous sequences of the reference." Applicants traverse.

The preamble of the rejected claims recite that the ob polypeptides recited in the claims are capable of modulating body weight. Thus, not "any and all sequences which could be made" fall within the scope of the claims. Furthermore, for the reasons described above, at least, the claimed molecules that do fall within the scope of the genus of the instant claims enjoy satisfactory written description support such that the instant specification conveys with reasonable clarity to those skilled in the art that, as of the filing date, Applicant was in possession of these weight modulatory isolated nucleic acid molecules. The rejection is in error and should be withdrawn.

Rejection under 35 U.S.C. § 112, first paragraph: enablement

Claim 77 stands rejected because the specification, while enabling an isolated or cultured cell comprising an expression vector, does not reasonably enable host cells in the context of a multicellular, transgenic organism, or as host cells intended for gene therapy. Further, the

Examiner asserts that the instant specification does not enable the skilled artisan to make and use the invention commensurate with the scope of the claims. In an attempt to shore up the enablement rejection, the Examiner at contends at length that there are no "methods or working examples" demonstrating transplantation of cells expressing an OB polypeptide for a therapeutic purpose or where gene therapy is performed on a human, and insists that the alleged unpredictability associated with gene expression in transgenic animals would necessitate undue experimentation in order to employ such host cells for generating a transgenic animal or providing for expressing an OB nucleic acid in a cell of an organism for gene therapy. The Examiner continues to assert that "the unpredictability in the art is *very high* for making transgenic animals"(emphasis in original) for the reasons set forth in the previous Action.

Applicants again traverse the rejection:

Relevant Law

To satisfy the enablement requirement of 35 U.S.C § 112, first paragraph, the specification must teach one of skill in the art to make and use the invention without undue experimentation. *Atlas Powder Co. v. E.I. DuPont de Nemours*, 750 F.2d 1569, 224 USPQ 409 (1984). This requirement can be met by providing sufficient disclosure, either through illustrative examples or terminology, to teach one of skill in the art how to make and how to use the claimed subject matter without undue experimentation. This clause does not require "a specific example of everything *within the scope* of a broad claim." *In re Anderson*, 176 USPQ 331, at 333 (CCPA 1973), emphasis in original. Rather, the requirements of § 112, first paragraph "can be fulfilled by the use of illustrative examples or by broad terminology." *In re Marzocci et al.*, 469 USPQ 367 (CCPA 1971). Further, because "it is manifestly impracticable for an applicant who discloses a generic invention to give an example of every species falling within it, or even to name every such species, it is sufficient if the disclosure teaches those skilled in the art what the invention is and how to practice it." *In re Grimme, Keil and Schmitz*, 124 USPQ 449, 502 (CCPA 1960).

Further, "any analysis of whether a particular claim is supported by the disclosure in an application requires a determination of whether that disclosure, when filed, contained sufficient information regarding the subject matter of the claims as to enable one skilled in the pertinent art to

make and use the claimed invention. The test of enablement is whether one skilled in the art could make of use the claimed invention from the disclosures in the patent coupled with information known in the art without undue experimentation." United States v. Telectronics, Inc., 857 F.2d 778, 8 USPQ2d 1217 (Fed. Cir. 1988); In re Stephens, 529 F.2d 1343, 188 USPQ 659 (CCPA 1976).

Furthermore, "a patent need not teach, and preferably omits, what is well known in the art. Spectra-Physics, Inc. v. Coherent, Inc., 827 F.2d 1524, 3 USPQ2d 1737 (Fed. Cir. 1987). . . . The fact that experimentation may be complex does not necessarily make it undue, if the art typically engages in such experimentation." M.I.T. v. A.B. Fortia, 774 F.2d 1104, 227 USPQ 428 (Fed. Cir. 1985).

Analysis

Claim 77 is directed to host cells transformed with an expression vector encoding an OB polypeptide-polyaminoacid polymer fusion protein. As described above, and contrary to the Examiner's contention, the instant specification need not provide a "working example" of every specific embodiment contemplated by the claims; furthermore the claims may be enabled by constructive or prophetic examples and teachings. The instant application teaches, for example, the following: a number of suitable cell and tissue types from which host cells may be selected for transformation with the inventive expression vectors, including mammalian host cells and human cells in tissue culture; parameters, such as copy number, nature of expression control sequences, etc., which may be considered in the selection and design of vectors suitable for host cell transformation; routes of administration which may be selected for host cell transplantation and gene therapy; and methods of generating transgenic animals and for providing gene therapies that employ the inventive host cells or expression vectors (see, e.g., page 42, line 3 through page 43 line 6; page 64, line 16 through 65, line 7; page 65, line 20, through page 67, line 3). With respect to the Examiner's lengthy comments throughout the Action concerning the alleged unpredictability of transgene expression efficacy in transgenic animals and in gene therapy, Applicant notes no recitation concerning efficacy exists in the claims. Furthermore, notwithstanding any such variability in efficacy, the claimed host cells would, nonetheless, still constitute host cells as recited in the instant claims. In this regard, and with respect to the

Examiner's allegations concerning applicant's alleged lack of provided evidence to the contrary to her assertions, Applicant contends that Applicant's rebuttal alone suffices to overcome the Examiner's attempt to establish a prima facie case for lack of enablement of the rejected claims. Applicant contends that no further evidence is required to be provided on the part of Applicant. Rather, it is the Examiner who must provide evidence to successfully rebut Applicants assertions, which the Examiner has not done. The Examiner does not refute the fact that the claimed cells, whether in the context of an intact organism or not, nonetheless remain host cells as instantly claimed. The Examiner does not provide evidence to refute Applicant's assertion that techniques for implantation of transformed cells into an intact organism were well within the purview of the skilled artisan.

Applicant is entitled to claims that are commensurate in scope not only with what applicant has specifically exemplified, but commensurate in scope with that which one of skill in the art could obtain by virtue of that which the applicant has disclosed. It is respectfully submitted that for the reasons provided supra, the skilled artisan, equipped with the teachings of the instant application in conjunction with techniques and knowledge available in the art, could practice the claimed invention without undue experimentation.

The claims are fully enabled. Accordingly, rejection under 35 U.S.C. § 112, first paragraph, should be withdrawn.

Provisional rejection under the judicially created doctrine of obviousness-type double patenting

Claims 61-67 and 69-88 remain rejected, and 89-102 are now rejected as provisionally rejected in previous Office Actions under the judicially created doctrine of double patenting as being unpatentable over claims 1-27 of U.S. Patent No. 5,935,810 and claims 1-21 of U.S. Patent No. 6,309,853. The outstanding Office Action now holds that the claims are additionally rejected in view of David et al. (U.S. Patent No. 4,179,337) and Stahl et al. (U.S. Patent No. 5,470,843).

In response to Applicants previous arguments of record, which are herein incorporated by reference, the Examiner acknowledges that the instant claims are not identical to those of the '810 and '853 patents, while nonetheless reiterating that they are encompassed by the claims of

'810 and '853, because "the proteins [encoded by the nucleic acids claimed in '810 and '853 use comprising language and therefore, conceivably include additional amino acids, such as polyaminoacids." In an effort to shore up the rejection, the Examiner now looks to Davis et al. and Stahl et al., urging that the references "teach that coupling of biologically active polypeptides to polymers is beneficial to increase the stability and circulation time of the amino acids as well as decreasing immunogenicity (see columns 1-2)," and "that polymers which are suitable of in vivo use include polyamino acids (see column 7, lines 4-13)," respectively. From this, the Examiner alleges, "it would have been *prima facie* obvious to attach a polymer, *specifically a polyaminoacid*, to the leptin molecule of the '810 or '853 patent for the advantage of increase stability and circulation time as well as for decreased inmmunogenicity (emphasis added)." The Examiner then extends this logic to allege that, "because polyaminoacids can be encoded by a nucleic acid, it also would have been obvious to make such molecules using a nucleic acid that encoded a fusion protein of leptin (OB) and the polyaminoacid polymer." This rejection is respectfully traversed.

Further, in reiterating her rejection, the Examiner continues to cite alleged teachings of the specification of these references in support of her continued contention that the instant claims are obvious in view of the claims of the cited patents. As stated in Applicant's previous response, and as reproduced below, it is unacceptable to refer to the cited reference in terms of what the disclosures in the specifications allegedly teach. Comparison of the instant claims may be made only to what subject matter is claimed in the earlier cited patents in order to provide a basis for an obviousness-type double patenting rejection:

Relevant law

The disclosure of a patent cited in support of a double patenting rejection cannot be used as though it were prior art even where the disclosure is found in the claims. Obvious-type double patenting signifies that the difference between a first-patented invention and its variant involves only an unpatentable difference, such that grant of the second patent would extend the right of exclusivity conferred by the first patent. Comparison can be made only with what subject matter is claimed in the earlier patent, paying careful attention to the rules of claim interpretation to

determine what invention a claim defines and not looking to the claim for anything that happens to be mentioned in it as though it were a prior art reference. A fundamental rule of claim construction requires that what is claimed is what is defined by the claims taken as a whole, every claim limitation is material. General Foods Corp. v. Studiengesellschaft Kohle mbH, 23 USPQ 1839 (Fed. Cir. 1992).

Double-patenting has not been found in instances in which the claims at issue do not embrace the prior patent compounds and/or the claims in the prior patent do not suggest any modification that would have produced the claimed compounds in the patent or application at issue (see, e.g., Ortho Pharmaceutical Corp v. Smith, 22 USPQ2d 1119 (Fed. Cir. 1992), in which obvious-type double patenting was not found in an instance in which the claims in the patent at suit were directed to compounds that did not encompass, structurally, the compounds claimed in the prior patents, and the compounds claimed in the prior patents did not suggest a modification of those compounds to produce compounds claimed in the patent at suit).

Thus, obvious-type patenting does not exist if the claims at issue do not encompass the claimed subject matter in the cited prior patent claims, and/or the claims in the prior patents do not suggest a modification to produce the claims in the subject application.

Analysis

The pending claims would not extend the right of exclusivity of the claims of U.S. application Serial No. 08/947,801

As discussed above, obviousness-type double-patenting is determined using the principles of claim interpretation. In an obviousness-type double-patenting analysis, the scope and content of a patent claim is determined relative to a claim in the application at issue; the differences between the two claims are determined; and the reasons why one of skill in the art would conclude that the claim in issue is an obvious variation of the cited patent claim that would extend the right of exclusivity of the cited patent claim are set forth (MPEP §804). While the specification of the cited patent(s) can always be used to ascertain the meaning of a term in the cited patent claim (*In re Boylan*, 392 F.2d 1017, 157 USPQ 370 (CCPA 1968)), and portions of the specification that provide support for the claims may also be examined (*In re Vogel*, 422 F.2d

438, 441-42, 164 USPQ 619, 622 (CCPA 1970)), the disclosure(s) of the cited patent(s) may not be used as prior art (MPEP §804).

Applicant initially notes that the entirety of the Examiner's support in the outstanding Office Action for the rejection relies on a treatment of the patents as prior art documents. Indeed, every reference to a passage in the references refers to alleged teachings or suggestions of the specification, rather than relying on the subject matter recited in the issued claims. Furthermore, the Examiner has failed to provide any nexus between the cited passages and any determination of the scope and content of any of the issued claims in the cited patents. Thus, the obviousness-type rejection is improper on its on its face on this basis alone. Nonetheless, in order to remove all doubt, Applicant traverses the provisional rejection for the reasons set forth below.

In the instant case, the claims as amended herein specifically recite that the claimed isolated nucleic acids encode a fusion protein capable of modulating body weight, and that they comprise a polynucleotide sequence encoding an OB polypeptide, which polynucleotide sequence is joined in frame to at least one polynucleotide sequence encoding an at least one polyaminoacid polymer. The claims in both U.S. Patent Nos. 5,935,810 and 6,309,853 are silent with respect to any recitation that the polynucleotides and isolated nucleic acids encode a fusion protein, or that they comprise a polynucleotide sequence joined in frame to at least one polynucleotide sequence encoding at least one polyaminoacid polymer. Thus, claims as amended herein, which read on nucleic acid molecules that encode fusion proteins, do not embrace the molecules claim in U.S. Patent Nos. 5,935,810 and 6,309,853. Similarly, the claims '810 and '853 fail to suggest a modification of the therein-claimed polynucleotides and isolated nucleic acids to produce the isolated nucleic acid molecules claimed in the in the instant application. The claims of the '810 and '8563 patents, singly and when combined, fail to teach or suggest the molecules encompassed by the instant claims.

The cited secondary references relied upon by the Examiner to shore up the obviousness-type double patenting rejection fail to render obvious the patentably disctinct and unobvious improvements provided in the instant claims. The claims of Stahl et al. (US 5,470,843) read on carbohydrate-containing polymers. While the specification provides a litany of chemically and functionally diverse polymeric moieties, among which "polyaminoacids" are listed, which are

alleged to be suitable for attachment to carbohydrate moieties, the claims fail to teach or suggest the desirability of any such polymer over another, "specifically a polyaminoacid," as the Examiner suggests. Even assuming *arguendo* that the use of polyaminoacid polymers were suggested, the claimed polymers of Stahl et al. are recited to unequivocally comprise carbohydrate moieties; such an unequivocal requirement that the polymers be attached to a carbohydrate moiety is not embraced by the instant claims. The claims of Davis et al. (US 4,179,337), which read on water soluble polypeptide compositions that are necessarily coupled to a coupling agent comprising a polyethylene glycol or a polypropylene glycol,are similarly unavailing – the instant nucleic acid molecules encoding the fusion proteins of the instant claims simply do not embrace the molecules unequivocally comprising carbohydrate moieties as recited in the claims of Davis et al. Therefore, none of the claims of the secondary references, singly or when combined, teach or suggest a modification of the claimed molecules of the '810 or '853 references such that the OB-fusion protein encoding molecules encompassed by the instant claims would result.

In view of the foregoing, the Examiner has failed to properly set forth a prima facie case of obviousness-type double patenting. Accordingly, the provisional rejection should be withdrawn.

Notwithstanding the above, if the Examiner insists that the provisional obviousness-type double patenting rejection should stand, Applicant respectfully requests deferral of the issue until an indication that there is allowable subject matter in the instant case. Until that time, the propriety of the rejection cannot be finally and properly assessed.

In conclusion, all rejections outlined in the outstanding Office Action are in error and should be withdrawn.

Applicants believe that all issues raised in the Office Action have been properly addressed in this response and in the amendments to the claims as shown in the attached Listing of Claims. Accordingly, reconsideration and allowance of the amended claims is respectfully requested. If the Examiner feels that a telephone interview would serve to facilitate resolution of any outstanding issues, the examiner is encouraged to contact Applicants' representative at the telephone number below.

CONCLUSION

No additional fees are believed due for this submission. However, if a fee is due, the Commissioner is hereby authorized to charge payment of any fees associated with this communication, to Deposit Account 19-4293 referencing Docket No. 16454.0004 C1. Additionally, the Commissioner is hereby authorized to charge payment or credit overpayment of any fees during the pendency of this application to Deposit Account 19-4293.

Respectfully submitted,

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